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10/037,526	01/04/2002	Harold Mermelstein	JWB-2001-1-P	7302

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EXAMINER

BENNETT, RACHEL M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/037,526

Applicant(s)

MERMELSTEIN ET AL.

Examiner

Rachel M. Bennett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 7-12 and 19-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 13-15, 16-18, 25-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group I in Paper No. 3 is acknowledged. Applicants have also elected species: **evening primrose and chasteberry**. The traversal is on the ground(s) that Applicants disagree that the product claims in Group I define an invention which is distinct from the invention defined by the process in Group II. In view of the prior art, the restriction requirement has been modified to include method claims. Claims that read on the elected species include 1-6, 13-15, 16-18, 25-31 which are drawn to the species evening primrose and chasteberry.

The requirement is still deemed proper and is therefore made FINAL.

### *Specification*

### *Claim Objections*

2. Claims 5 and 6 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 2 reads "a therapeutic composition of claim 1 further including an effective amount of antibacterial agent". Claim 5 reads "a therapeutic composition as in claim 2 further including an effective amount of antibacterial agent". Claim 3 reads "a therapeutic composition as in claim 2 wherein said anti-bacterial agent is selected from the group consisting of methyl paraben, propyl paraben, imidazolidinyl urea and mixtures thereof". Claim 6 reads "a therapeutic composition as in claim 3 wherein said anti-bacterial

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agent is selected from the group consisting of methyl paraben, propyl paraben, imidazolidinyl urea and mixtures thereof". Clarification is required.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-6, 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newmark et al. (US 6242012), and further in view of Gehling et al. (US 2003/0045829 A1) and Remington's Pharmaceutical Science.

Applicants claim a therapeutic composition for treatment of vaginal dryness comprising an effective amount of at least two herbal compounds selected from evening primrose and chasteberry, said two herbal compounds used in combination with olive oil, flax seed oil, or unseeded flax oil, distilled water, propylene glycol and an effective amount of thickening agent to make said composition in gel form.

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Newmark et al. discloses a herbal composition which can be used to alleviate the symptoms associated with hormonal imbalance in women contains supercritical extracts of ginger, rosemary and evening primrose oil, and either regular or supercritical extracts of black cohosh, gong quai, achizandra berry, chaste tree berry and rosemary. The herbal composition can be administered topically. In addition to promoting hormonal balance, the herbal composition also sustains warmth and normal fluids for healthy sexual functioning. See abstract. Newmark discloses an herbal composition which is capable of relieving symptoms associated with pre- and postmenopausal hormonal imbalance. The formulation combines the following features: lipoxxygenase inhibiting constituent compounds (ginger, rosemary); empirically reversed normalizers of hormonal functioning (black cohosh, vitex (chasteberry)); essential fatty acid modulators (evening primrose oil, olive oil) and systemic mood/energy support. See col. 1, lines 12-59. The herbal composition can be applied topically, specifically, ophtamically, vaginally, rectally, intranasally, and the like. When applied topically, the composition is particularly effective in relieving vaginal dryness and improving skin tone. See col. 6, lines 37-48. Formulation for topical administration may include but not limited to lotions, ointments, gels, creams, suppositories, drops, liquids, sprays or powders. Conventional pharmaceutical carriers; aqueous, powder, or oily bases; thickeners may be necessary or desirable. See col. 7, lines 40-47. While Newark teaches both evening primrose and chasteberry in a topical composition, specifically a gel, Newmark does not disclose the composition to include an antibacterial agent. Furthermore, Newmark does not disclose the composition to include propylene glycol.

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Gehling et al. disclose a tampon is adapted to deliver a therapeutic agent. See abstract. Alternatively, or in addition, therapeutic and other beneficial agents such as antibacterial agents may be similarly delivered. See page 5, [0052]. Known antibacterial agents in the art are methyl paraben and propyl paraben. Examples of beneficial botanicals may include Agnus castus (Chasteberry) and evening primrose. These botanicals can be combined with other beneficial agents. These beneficial therapeutic agents promote epithelial health in the vaginal region by delivering botanical ingredients with a feminine care device. The idea is to modulate the vaginal environment to enhance the wellness of this anatomical region. These benefits can be rather simple, for example increasing comfort by providing moisturization and/or lubricity. See page 6, [0056]-[0058]. Preparations may include gel, botanical oil in an anhydrous base or polyethylene glycol based system. See page 6, [0059]. Combining the active ingredients with a hydrophobic material such as a solidifying agent; wax, vegetable oil, natural soft material (i.e. cocoa butter), allows gradual diffusion of the active ingredient from the hydrophobic material to the body of the wearer. See page 7, [0068].

Remington's Pharmaceutical Sciences discloses propylene glycol as a humectant, which is a substance that promotes retention of moisture.

Absent unexpected results, it is the position of the examiner it would have been obvious at the time the invention was made to have modified the composition of Newmark to add antibacterial agents as taught by Gehling and propylene glycol as taught by Remington's because of the expectation of fighting bacterial infections with the antibacterial agent as taught by Gehling and promoting retention of moisture as taught by Remington's.

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6. Claims 16-18, 25-27, 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newmark et al. (US 6242012), and further in view of Gehling et al. (US 2003/0045829 A1) and Remington's Pharmaceutical Science.

Applicants claim a therapeutic composition in suppository form, for treatment of vaginal dryness comprising an effective amount of at least two herbal compounds selected from evening primrose and chasteberry, said two herbal compounds used in combination with olive oil, propylene glycol and a wax, specifically cocoa butter.

Newmark et al. discloses a herbal composition which can be used to alleviate the symptoms associated with hormonal imbalance in women contains supercritical extracts of ginger, rosemary and evening primrose oil, and either regular or supercritical extracts of black cohosh, gong quai, achizandra berry, chaste tree berry and rosemary. The herbal composition can be administered topically. In addition to promoting hormonal balance, the herbal composition also sustains warmth and normal fluids for healthy sexual functioning. See abstract. Newmark discloses an herbal composition which is capable of relieving symptoms associated with pre- and postmenopausal hormonal imbalance. The formulation combines the following features: lipoxygenase inhibiting constituent compounds (ginger, rosemary); empirically reversed normalizers of hormonal functioning (black cohosh, vitex (chasteberry)); essential fatty acid modulators (evening primrose oil, olive oil) and systemic mood/energy support. See col. 1, lines 12-59. The herbal composition can be applied topically, specifically, ophtamically, vaginally, rectally, intranasally, and the like. When applied topically, the composition is particularly effective in relieving vaginal dryness and improving skin tone. See col. 6, lines 37-48. Formulation for topical administration may include but not limited to lotions, ointments,

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gels, creams, suppositories, drops, liquids, sprays or powders. Conventional pharmaceutical carriers; aqueous, powder, or oily bases; thickeners may be necessary or desirable. See col. 7, lines 40-47. While Newark teaches both evening primrose and chasteberry in a topical composition, specifically a suppository, Newmark does not disclose the composition to include an antibacterial agent. Furthermore, Newmark does not disclose the composition to include propylene glycol or wax.

Gehling et al. disclose a tampon is adapted to deliver a therapeutic agent. See abstract. Alternatively, or in addition, therapeutic and other beneficial agents such as antibacterial agents may be similarly delivered. See page 5, [0052]. Known antibacterial agents in the art are methyl paraben and propyl paraben. Examples of beneficial botanicals may include Agnus castus (Chasteberry) and evening primrose. These botanicals can be combined with other beneficial agents. These beneficial therapeutic agents promote epithelial health in the vaginal region by delivering botanical ingredients with a feminine care device. The idea is to modulate the vaginal environment to enhance the wellness of this anatomical region. These benefits can be rather simple, for example increasing comfort by providing moisturization and/or lubricity. See page 6, [0056]-[0058]. Preparations may include gel, botanical oil in an anhydrous base or polyethylene glycol based system. See page 6, [0059]. Combining the active ingredients with a hydrophobic material such as a solidifying agent; wax, vegetable oil, natural soft material (i.e. cocoa butter), allows gradual diffusion of the active ingredient from the hydrophobic material to the body of the wearer. See page 7, [0068].

Remington's Pharmaceutical Sciences discloses propylene glycol as a humectant, which is a substance that promotes retention of moisture.



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Absent unexpected results, it is the position of the examiner it would have been obvious at the time the invention was made to have modified the composition of Newmark to add antibacterial agents and wax, such as cocoa butter as taught by Gehling and propylene glycol as taught by Remington's because of the expectation of fighting bacterial infections with the antibacterial agent and as taught by Gehling and promoting retention of moisture as taught by Remington's. Furthermore, it would have obvious to add a wax, such as cocoa butter as taught by Gehling, to Newmark since both Gehling and Newmark teach a suppository composition and coca butter is taught by Gehling to be used in suppository compositions.

### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

R. Bennett  
June 12, 2003

THURMAN K. PAGE  
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